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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,966	11/27/2001	Michael Rohan	PP-016337.004	8065

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CHIRON CORPORATION
INTELLECTUAL PROPERTY - R440
PO BOX 8097
EMERYVILLE, CA 94662-8097

EXAMINER

YU, MISOOK

ART UNIT PAPER NUMBER

1642

DATE MAILED: 01/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/993,966

Applicant(s)

ROHAN ET AL.

Examiner

MISOOK YU, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 23-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: See Continuation Sheet.

Continuation of Attachment(s) 6). Other: Exhibit A (sequence alignment) .

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of group 1, claims 1-22 in the reply filed on 10/22/2004 is acknowledged.

Claims 23-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Claims 1-38 are pending. Claims 1-22 are examined on merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 9, and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4, and 9 are confusing as to the property boundary set by the limitation "the coding region of SEQ ID NO:5" because claim 9 recites "the 1416 nucleotides that constitute the coding region of SEQ ID NO:5", but this definition contradicts with the disclosure of specification at Fig. 1-1 to Fig. 1-3, where it discloses that the coding region starts with the codon ATG, and ends with TAG, which is a stop codon. The instant SEQ ID NO:5 encodes the human protein of SEQ ID NO:7, which is 470 amino acids in length. Based on the simple calculation of 470×3 (a codon for each of the 470 amino acids) + 3 (stop codon) = 1413, the 1413 nucleotides between ATG at nucleotide

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224 to # 1636 of instant SEQ ID NO:5 should constitute the coding region of SEQ ID NO:5 according to specification at Fig. 1-1 to Fig. 1-3.

For the purpose of this Office action, the Office assumes that 1413 nucleotides constitute the coding region of SEQ ID NO:5. However, this treatment does not relieve applicant the burden of responding to this rejection.

The property boundary set by claim 13 as currently construed is vague and confusing because the limitations, i.e. "at least one conservative amino acid substitution" and "said polypeptide comprises an amino acid sequence selected from" the four choices listed as (a)-(d) contradict each other.

The specification at paragraph [0074] discloses "Percent conservation is calculated from the above alignment by adding the percentage of identical residues to the percentage of positions at which the two residues represent a conservative substitution (defined as having a log odds value of greater than or equal to 0.3 in the PAM250 residue weight table). Conservation is referenced to human Nkd when determining percent conservation with non-human Nkd, e.g. mNkd, when determining percent conservation. Conservative amino acid changes satisfying this requirement are: R-K; E-D, Y-F, L-M; V-I, Q-H." This disclosure indicates that "at least one conservative amino acid substitution" is within amino acids 2 to 460, or 1-460 of SEQ ID NO:7 since the limitation "substitution" requires a reference amino acid in this case, amino acids 2 to 460, or 1-460 of SEQ ID NO:7. However, the limitation "said polypeptide **comprises**" an amino acid sequence selected from one of the four Markush group members, which one of them is the polypeptide comprising the amino acids 2 to 460 of SEQ ID NO:7.

For purpose of this Office action, the scope of the claimed nucleic acid includes nucleic acid molecule encoding at least one amino acid substitution within the amino acids 2 to 460 of SEQ ID NO:7. However this treatment does not relieve applicant the burden of responding to this rejection.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5-9, 10-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The applicable standard for the written description requirement can be found: MPEP 2163; University of California v. Eli Lilly, 43 USPQ2d 1398 at 1407; PTO Written Description Guidelines; Enzo Biochem Inc. v. Gen-Prove Inc., 63 USPQ2d 1609; Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111; and University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 (CA FC 2004).

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics,

structure/function correlation, methods of making the claimed product, or any combination thereof.

In this case, the only factor present in the claims is a partial structure of in the form of % identity or partial structure in form of a partial cDNA fragment with the open transitional phrase encoding a partial protein of a full-length protein. The present claims encompass full-length genes and cDNAs (such as differently spliced isoforms of said full-length gene) that are not further described. There is substantial variability among the species of DNA s encompassed within the scope of the claims because amino acids 1, or 2 to 460 of SEQ ID NO:7 is a fragment (a partial structure) of a full length protein encoded by a cDNA species. They are structurally unrelated. A description of a genus of cDNA may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequences, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.

The claimed partial structures are not associated with any other physical and/or chemical properties, functional characteristics. There is no sufficient distinguishing identifying characteristics of the genus. There is no structure/function correlation of the genus. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Claim 13 lacks written description because the polypeptides with at least one conservative amino acid substitution is not associated any other associated with any

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other physical and/or chemical properties, functional characteristics. It is noted all of amino acids 2 to 460 or 1 to 460 could be changed to be within the boundary of set by instant claim 13. AS for the limitation in claim 13 (c) and (d), the specification does not teach how the structure of a non-human primate homologue of SEQ ID NO:7 looks like.

Claims 14-22 lacks written description for the same reason as the base claims they depend on.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of nucleic acid molecules, given that the specification has only described SEQ ID NO: 5 and 1. Therefore, only isolated nucleic acid comprising SEQ ID NO:1 and 5, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 5-8, and 10-22 are rejected under 35 U.S.C. 102(e) as being anticipated by US Pat. 6,630,323 (effective filing date: Feb. 17, 1999, filing date: February 17, 2000, issue date: Oct. 7, 2003).

Claims 1, 5-8, and 10-22 are interpreted as drawn to an isolated nucleic acid comprising a polynucleotide that is at least 90% identical to a polynucleotide encoding a polypeptide comprising amino acids 1 to 460 of SEQ ID NO:7 (claim 1), or at least one amino conservative amino acid substitution in said polypeptide (claim 13), comprising at least **50** (claim 5), **200** (claim 6), **500** (claim 7), or **750** (claim 8) contiguous nucleotides of the coding region of SEQ ID NO:5, at least 90% (claim 10), or 95% (claims 11, and 12) identical to the coding region of SEQ ID NO:5, wherein a recombinant vector comprising said nucleic acid operatively linked to a promoter is claimed in claims 14-16, and a host comprising said recombinant vector is claimed in claims 17-19, and a method of producing a polypeptide using said host cell is claimed in claims 20-22.

US Pat. 6,630,323 teaches an isolated nucleic acid, i.e. SEQ ID NO:5 comprising a polynucleotide that is at least 90% identical to a polynucleotide encoding a polypeptide comprising amino acids 1 to 460 of SEQ ID NO:1, or at least one amino conservative amino acid substitution in said polypeptide, comprising at least **50**, **200**, **500** or **750** contiguous nucleotides of the coding region of SEQ ID NO:5, at least 90%, or 95% identical to the coding region of SEQ ID NO:5. Note the attached Exhibit A

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(sequence alignment) that the coding region of SEQ ID NO:5 is 99.8% identical to the coding region of instant SEQ ID NO:5. There is only one amino acid difference between the instant SEQ ID NO:7 and the protein encoded by SEQ ID NO:5 of US Pat.

6,630,323, i.e. Ser to Phe change at amino acid 290 of the instant SEQ ID NO:7. Since the specification does not define which amino acid is the conservative substitution of Ser, the Office broadly interprets that Phe is a conservative substitution since both are neutral amino acids.

US Pat. 6,630,323 teaches a recombinant vector comprising nucleic acid encoding NKD polypeptide which is encoded by SEQ ID NO:5, wherein in said nucleic acid is operatively linked to a promoter, and a host comprising said recombinant vector, a method of producing said polypeptide using said host cell. Note column 6, line 22 to column 7, line 24.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey C Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D.
Examiner
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A handwritten signature in black ink, appearing to read 'Misook Yu', with a stylized flourish at the end.

**MISOOK YU
PATENT EXAMINER**

QY 1 MetGlyLysLeuHisSerLysProAlaAlaValCysLysArgArgGluSerProGluGly 20
 Db 8 ATGGAGAACTTCACTCCAAAGCCGGCGCGTGTGCAAGCGCAGGAGAGCCCGGAGGT 67
 QY 41 AspSerPheAlaValSerAlaAlaTTPAlaArgLysGlyLeuGluThrPheArg 40
 Db 68 GACAGCTTCGCGCTGAGCGGTGCTGGGCTCGGAAGGCGATCAGGAGTGATCGGAGA 127
 QY 41 GlnArgCysProGlyGlyValSerGlyProArgGlnLeuArgLeuAlaGlyThrLeuGly 60
 Db 128 CAGCGTGGCGGCGGTGTCTCGGACCCGACAGCTGCGGTTCGGGCGCACCATAGGC 187
 QY 61 ArgSerThrArgGluLeuValGlyAspValLeuArgAspThrLeuSerGluGluGlu 80
 Db 188 CGAAGCACCCGGAGCTCGTGGCGAGCTGTGAGAGACACGCTCAGCGAGGAGGAG 247
 QY 81 AspAspPheArgLeuGluValAlaLeuProProGluLysThrAspGlyLeuGlySerGly 100
 Db 248 GACGACTTTCGCTGGAAGTGGCCCTGCTCTGAGAACATGACGGGTGGGCGACCGA 307
 QY 101 AspGluLysLysMetGluArgValSerGluProCysProGlySerLysLysGlnLeuLys 120
 Db 308 GATGAGAAGAATGAGAGAGTGAAGCAACCTGCCCCAGGCTCCAAAGAGCAGCTGAAG 367
 QY 121 PheGluGluLeuGlnCysAspValSerMetGluGluAspSerArgGlnGluThrPhe 140
 Db 368 TTTGAAGAGCTTCAGTGGCGAGCTGCTATGGAGGAGCAGCGCGCAGGTGGACCTTC 427
 QY 141 ThrLeuTyrAspPheAspAsnGlnLysValThrArgGluAspIleThrSerLeuLeu 160
 Db 428 ACCCTGTATGACTTTGACACACACCGCAGGTGTCACCGAGAGGACATCACCAGCTTGTG 487
 QY 161 HisThrIleTyrGluValValAspSerSerValAsnHisSerProThrSerSerLysMet 180
 Db 488 CACACCACTATGAGTGGTGGTGGTCTCTGTCAACCACTCCCAACATCCAGCAGATG 547
 QY 181 LeuArgValLysLeuThrValAlaProAspGlySerGlnSerLysArgSerValLeuVal 200
 Db 548 CTGGGGTAAAGCTTACCGTGGCGCCCGATGGCAGCCAGAGCAAGAGGAGCGTCTGTG 607
 QY 201 AsnGlnAlaAspLeuGlnSerAlaArgProArgAlaGluThrLysProThrGluAspLeu 220
 Db 608 AATCAGGCTGACCTGCGAGCGCAGCGCCCGCAGCAGAGCAAGCCCTCAGGAGCCTG 667
 QY 221 ArgSerTrpGluLysLysGlnArgAlaProLeuArgPheGlnGlyAspSerArgLeuGlu 240
 Db 668 CGGAGCTGGGAGAGAGCAGCGCGCGCTCAGGTTCCAGGCTGACAGCGCGCTGGAG 727
 QY 241 GlnSerGlyCysTyrHisHisCysValAspGluAsnIleGluArgArgAsnHisTyrLeu 260
 Db 728 CAGTCTGGCTGCTACCACTTGGTAGTAGAAGCAATCGAGAGGAGAGAAACCACTACTTA 787
 QY 261 AspLeuAlaGlyIleGluAsnTyrThrSerGlnPheGlyProGlySerProSerValAla 280
 Db 788 GATCTCGCCGGGATAGAAACTACAGCTCCCAATTTGGGCTGGCTCCCTCCGTTGGCC 847
 QY 281 GlnLysSerGluLeuProProArgThrSerAsnProThrArgSerArgSerHisGluPro 300
 Db 848 CAGAAGTCAGAACTGCCCCCGCCAGCTTCAATCCCACTCGATCTCGCTCCCACTAGCCG 907
 QY 301 GluAlaIleHisIleProHisArgLysProGlnGlyValAspProAlaSerPheHisPhe 320
 Db 908 GAAGCCATCCATCCACACCCAGAAAGCCCAAGGCGTGGAGCCCGGCTCTTCCACTTC 967
 QY 321 LeuAspThrProIleAlaLysValSerGluLeuGlnGlnArgLeuArgGlyThrGlnAsp 340
 Db 968 CTTGACACCCCAATCGCAAGGTCTCAGAGCTCCAGCAAGCGCTCCGGGCGACTCAGGAC 1027
 QY 341 GlySerLysHisPheValArgSerProLysAlaGlnGlyLysSerValGlyValGlyHis 360
 Db 1028 GGAGGCAAGCACTTTGTAGGTCTCCCAAGGCCAGGCGCAGAGTGTGGTGTGGGCCAC 1087
 QY 361 ValAlaArgGlyAlaArgAsnLysProProLeuGlyProAlaIleProAlaValSerPro 380

Db 1088 GTGGCCAGAGGGGCAAGAAACCAAGCCCTCTGGGACCCGCCATCTCTGGGTGTCCCC 1147
 QY 381 SerAlaHisLeuAlaAlaSerProAlaLeuLeuProSerLeuAlaProLeuGlyHisLys 400
 Db 1148 TCGGCCACCTGGCTGCCAGCCCGGCCCTCTCTCCCTTACCCCTTGGGCGCACAG 1207
 QY 401 LysHisLysHisArgAlaLysGluSerGlnGlnGlyCysArgGlyLeuGlnAlaProLeu 420
 Db 1208 AAGCAACAGCAGCAGGCAAGGAGAGGAGGAGGAGGAGGAGGAGGAGGAGGAGGAG 1267
 QY 421 AlaSerGlyGlyProValLeuLeuArgGluHisLeuArgGluLeuProAlaLeuVal 440
 Db 1268 GCTCAGGTGGCCCTGTCTGGGCGGAGGAGGAGGAGGAGGAGGAGGAGGAGGAGGAG 1327
 QY 441 TyrGluSerGlnAlaGlyGlnProValGlnArgHisGlnHisHisHisHisHisHis 460
 Db 1328 TATGAGAGCCAGGCGGGCAGCGGCTCAGAGACATGATGACACCAACCATGACAT 1387
 QY 461 HisHisHisTyrHisHisPheTyrGlnThr 470
 Db 1388 CACCACCATTTACCACTTCTTACCAGACA 1417

US-09-506-066E-3
 ; Sequence 3, Application US/09506066E
 ; Patent No. 6630323
 ; GENERAL INFORMATION:
 ; APPLICANT: Scott, Matthew
 ; APPLICANT: Wharton, Keith
 ; APPLICANT: Zeng, Wenlin
 ; TITLE OR INVENTION: Naked Cuticle Genes and their Uses
 ; FILE REFERENCE: STAN-121
 ; CURRENT APPLICATION NUMBER: US/09/506,066E
 ; PRIOR FILING DATE: 2000-02-17
 ; PRIOR APPLICATION NUMBER: 60/120,646
 ; PRIOR FILING DATE: 1999-02-17
 ; NUMBER OF SEQ ID NOS: 15
 ; SOFTWARE: FastSeq for Windows Version 4.0
 ; SEQ ID NO 3
 ; LENGTH: 1731
 ; TYPE: DNA
 ; ORGANISM: Mus musculus
 ; FEATURE:
 ; NAME/KEY: CDS
 ; LOCATION: (140)...(1553)
 ; OTHER INFORMATION: Nkdl coding sequence
 US-09-506-066E-3

Alignment Scores:
 Pred. No.: 3,46e-178 Length: 1731
 Score: 2174.50 Matches: 407
 Percent Similarity: 90.64% Conservative: 19
 Best Local Similarity: 86.60% Mismatches: 43
 Query Match: 87.01% Indels: 1
 DB: 4 Gaps: 1

US-09-993-966-7 (1-470) x US-09-506-066E-3 (1-1731)
 QY 1 MetGlyLysLeuHisSerLysProAlaAlaValCysLysArgArgGluSerProGluGly 20
 Db 140 ATGGGGAACCTTCACTCGAAGCCCGCGCGTGTGCAAGCGCAGGAGAGCCCGAAGGT 199
 QY 21 AspSerPheAlaValSerAlaAlaTTPAlaArgLysGlyIleGluThrPheArg 40
 Db 200 GACAGCTTGTCTGTAAGCGCTGCTGGCAAGGAAAGGCAATCGAGAGTGGATCGGAGG 259
 QY 41 GlnArgCysProGlyGlyValSerGlyProArgGlnLeuArgLeuAlaGlyThrLeuGly 60
 Db 260 CAGCGCTGTCCAGGCGAGGCTCTCAGGACCCCGCTCAGCTGAGATGGCAGGCACTGTGT 319
 QY 61 ArgSerThrArgGluLeuValGlyAspValLeuArgAspThrLeuSerGluGluGlu 80